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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/659,451

09/09/2003

Maria Villani

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11/16/2007

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EXAMINER

SRIVASTAVA, KAILASH C

ART UNIT

PAPER NUMBER

1657

MAIL DATE

DELIVERY MODE

11/16/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/659,451

Applicant(s)

VILLANI, MARIA

Examiner

Dr. Kailash C. Srivastava

Art Unit

1657

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3,7,24 and 25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3,7,24 and 25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 1/31&6/11/2007.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_

## DETAILED ACTION

1. Request for continued examination (i.e., RCE) under 37 CFR §1.114, including the fee set forth in 37 CFR §1.17(e), was filed in this application on 19 July 2006 after a Final action mailed 02 June 2006 and a subsequent Advisory Action mailed 10 July 2006. Since this application is eligible for continued examination under 37 CFR §1.114, and the fee set forth in 37 CFR §1.17(e) has been timely paid, the finality of the previous Office action mailed 05 March 2007 has been withdrawn pursuant to 37 CFR §1.114. Accordingly, an RCE has been established and the action on RCE follows.
2. Response and amendment filed 31 January 2007 to Office Action mailed 19 October 2006 is acknowledged and entered.
3. Information filed 31 January 2007 in response to information request under 37 CFR §1.105 in Office Action mailed 19 October 2006 is acknowledged and entered.
4. Please note, the information submitted ( i.e., Page 77, English Translation of Russian written "Handbook on Cosmetics" Rozentul, M.A. (Ed.), Meditsina, 1964, Moscow) in response to information request under 37 CFR §1.105, however, only provides information on Acne and treatment of acne with preparations comprising antibiotic or mask of thistle diluted with hydrogen peroxide and method of scrubbing.

### Withdrawals in View of Applicants' Amendments and Arguments

5. In view of remarks and amendment filed 19 June 2006, the following objection in the Office Action mailed 02 June 2006 is hereby withdrawn:
  - o Objection to Claims 4, 6-7, 24-25 under 37 CFR §1.75(c) as being in improper form.
6. In view of remarks and amendment filed 19 June/ 19 July 2006, the following rejections in the Office Action mailed 02 June 2006 are hereby withdrawn:
  - o rejection to Claims 1, 3-4, 6-7 and 23-26 under 35 U.S.C. §112, first paragraph as failing to comply with written description requirements;
  - o anticipation rejection to Claims 1, 3-4, 7 and 24-25 under 35 U.S.C. §102 (a), as being anticipated by RU 2176511 C1 (the '511 reference).

Please note, contrary to assertion made in response filed 19 June/ 19 July 2006, this rejection is under 35 U.S.C. §102 (a), not under 35 U.S.C. §102 (b) (See Response filed 19 June 2006, Page 7, Line 23 or Response filed 19 July 2006, Page 7, Line 3).

### **General Informal Maters**

7. Please note, the Art Unit Location for instant application under prosecution at the United States Patent and Trademark Office (i.e., USPTO) has been changed to Art Unit 1657. Instant Application has been assigned to Dr. Kailash C. Srivastava in Art Unit 1657. To aid in correlating any papers for this application (i.e., 10/659,451), all further correspondence regarding this application should be directed to Examiner Kailash C. Srivastava in Art Unit 1657.

### **Claims Status**

8. According to the Claims listing filed 31 January 2007, the status of the claims is as follows:

(i) Claims 2, 4-6, 8-23 and 26 have been cancelled.

(ii) Claims 1, 3, 7 and 24-25 are pending.

9. Please note, in reviewing the entire file of instant application, following determination was made:

- a. in Claims listing, arguments and remarks filed 19 June 2006, a total of 27 Claims have been listed with Claim 27 as the newly added claim.
- b. in Claims listing, arguments and remarks filed 19 June 2006, a total of 26 Claims have been listed with Claim 27 as the newly added claim. Additionally, in remarks the description is, "As a result of this amendment claims 1, 3, 7, 23-25 and 27 remain pending in this application. Claim 27 has been added to further claim Applicant's invention (See, Remarks filed 19 June 2006, Page 4, Lines 15-16).
- c. in Claims listing filed 19 July 2006, and 31 January 2007 respectively, a total of only 26 Claims have been listed. Furthermore, while there is no mention of Claims status in the remarks filed 31 January 2007; the remarks filed 19 July 2006 states, "Claims 1, 3, 4, 6, 7 and 10-26 were pending in this application as of the mailing date of this Office Action. Claims 10-22 were previously withdrawn (See, Remarks, Page 4, Lines 9-10) and further mentions, "Claims 2, 5, 8 and 9 were previously canceled. Claims 4, 6, 23 and 26 are currently

canceled. (See, Remarks Page 4, Lines 12-13). The remarks filed 19 July 2006 also mention, As a result of this amendment, claims 1, 3, 7 and 24-25 remain pending in this application. (See, Remarks, Page 4, Lines 16-17).

Noteworthy is the fact, in Claim Listings filed 19 July 2006 and 31 January 2007, Claim 27 is not listed. Furthermore, in remarks filed 19 July 2006 the status for Claim 27 is not discussed. Accordingly, Clarification to the status for Claim 27 is respectfully solicited.

10. Since the current listing of Claims mentions only Claims 1-26 and status for Claim 27 is not mentioned, Claims 1, 3, 7 and 24-25 are examined on merits.

### **Information Disclosure Statement**

11. The Information Disclosure Statements (i.e., IDSs) filed 31 January and 11 June 2007 respectively have been made of record, considered and duly signed appropriate form (i.e., PTO 1449 or equivalent) enclosed.

### **Objection To Specification**

12. The specification is objected to because Line one of first page of specification, in its present form does not properly cite the application priority data. Please update the status of Priority to 10/186,996 as said application is now abandoned.

13. The specification is objected to because at different places in the specification, grammatically or idiomatically incorrect language (e.g., missing comma between the words "invention" and "an" at Line 1 of Page 15, Paragraph 0060; word, "presently" at Page 28, Line 18) has been presented. The specification should be carefully revised to comply with 35 U.S.C. §112, first paragraph.

The lengthy specification has not been exhaustively checked to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification. Please be advised to not include any new matter while correcting the specification for grammar/ idiom, or verbose language.

### **Objection To Claims**

14. Claims 1, 3, 7, 24 and 25 are objected to for the following reasons:

- the phrase “fresh water sponge of the species *Spongilla lacustris*”. *Spongilla lacustris* is the name of a sponge and includes both Genus and species. Thus, the phrase, with the word, “species” as currently presented is misleading and not according to the art-approved terminology. Appropriate correction is required;
- At line 1 of each of the Claims 3, 7, 24 and 25, before the word, “wherein” a “comma should be --,-- inserted.

All other claims depend directly or indirectly from the rejected Claim 1 and are, therefore, also objected for the reasons set forth above.

### **Objection To Abstract**

15. Legal language (e.g., “without limitation” or “embodiment”) should not be used in an abstract. See MPEP §608.01(b). Appropriate correction is required. Please be warned to not add any new matter while revising the abstract for suggested correction(s) or to eliminate any verbose or incorrect terms/language.

### ***35 U.S.C. § 112, Second Paragraph Rejection***

16. The following is a quotation of the second paragraph of 35 U.S.C. § 112:

*The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.*

17. Claim 25 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Phrases, “irrigation water” and “floral water” render Claim 25 incomprehensible, unclear, vague and therefore, indefinite, because:
  - (i). it is difficult to comprehend that one would apply “irrigation water” in a pharmaceutical composition; and
  - (ii). metes and bounds for the phrase, “floral” water are not defined.

Appropriate clarification/ correction is required.

### Claim Rejections Under 35 U.S.C. § 103(a)

18. The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office action:

*A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.*

19. Claims 1, 3, 7 and 24 are rejected under 35 U.S.C. § 103 (a) as obvious over combined teachings from RU 2 182 820 C1, issued 27 May 2002 (herein after referred as RUC1) in view CN 1152455, published 25 June 1997 (herein after referred as CN455).

Regarding Claims 1, 3, 7, and 24 RUC1 teaches a cosmetic cream comprised of as active ingredient powder of fresh water spongillidae among other components (English abstract, Lines 10-11) and application of said cream for prevention of premature skin aging and improving aging skin (Page 1, Column 2, Lines 11-12; Page 2, Column 1, Lines 1-3 and Page 2, Column 2, Lines 3-11 and 13-14). RUC1 does not teach that the freshwater spongillidae powder is obtained from a member of the Genus *Spongilla*.

CN455 teaches a composition comprising *Spongilla fragilla* as one of the raw materials, wherein said raw material is prepared by crushing and sieving. Note because of the preparation method employed to obtain the composition of CN455, and fact that *Spongilla fragilla* is of same taxonomic Genus as *Spongilla lacustris*, said composition intrinsically comprises a therapeutic composition comprising 50% to 60 insoluble material of the fresh water sponge because said composition describes in the prior art comprises the powder of a sponge from the same genus prepared in the same manner to produce the same product as is claimed in instant application (See e.g., *In re Best*, 195 USPQ 430, 433-CCPA 1977). Also note that the functional intended use of a composition does not carry any patentable weight.

One having ordinary skill in the art at the time of the claimed invention would have been motivated to modify/combine the teachings from RUC1 according to teachings from CN455 to obtain a composition comprising a substantially pure powder of a fresh water sponge and at least one pharmaceutically acceptable excipient wherein said powder is a powder of *Spongilla lacustris* comprising approximately 50%-60% insoluble material of said freshwater sponge, because RUC1 teaches a composition comprising a dry powder of freshwater spongillidae with a pharmaceutical excipient and CN455 teaches a pharmaceutical composition comprising crushed and sieved *Spongilla fragilla*.

Thus, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to modify teachings from RUC1 according to teachings from CN455 to obtain a composition comprising a powder of freshwater sponge with at least one pharmaceutically acceptable excipient because CN455 teaches a pharmaceutical composition comprising dry powder of *Spongilla fragilis*. Furthermore, *Spongilla lacustris* as well as *Spongilla fragilis* are both freshwater sponges and CN455 teaches preparing the powder of *Spongilla fragilis* in same steps as in instant application. Thus, CN455 remedies the deficiency in teachings from RUC1.

From the teachings of the references cited *supra*, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

### Conclusion

20. For the aforementioned reasons, no claims are allowed.

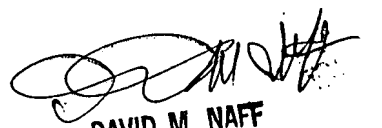
21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached at (571)-272-0925 Monday through Thursday 7:30 A.M. to 6:00 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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10 November 2007

  
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ART UNIT 128/1657